Reporting Adverse Reactions and HCT/P Deviations

FDA AND THE NEW PARADIGM FOR TISSUE REGULATION

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Food and Drug Administration

21 CFR 1271.350 - Reporting

(a) Adverse reaction reports

(b) Reports of HCT/P deviations

Adverse Reaction Reports

You must ***investigate any*** adverse reaction involving a communicable disease related to an HCT/P that you made available for distribution.

[21 CFR 1271.350(a)(1)]

Adverse Reaction Reports

You must ***report*** to FDA an adverse reaction involving a communicable disease if it

- Is fatal
- Is life-threatening
- Results in permanent impairment of function or perm damage to body structure; or
- Necessitates medical or surgical intervention, including hospitalization

When, Who, How?

- You must submit each report within 15 calendar days of initial receipt of the information
- Establishments that manufacture HCT/Ps or made HCT/Ps available for distribution
- Use Form FDA 3500A (MedWatch)

  Obtained from CBER, or electronically from www.fda.gov/medwatch or www.hhs.gov/forms

HCT/P Deviation means an event:
(21 CFR 1271.3(dd))

- That represents a deviation from applicable regulations in this part or from applicable standards or established specifications that relate to the prevention of communicable disease transmission or HCT/P contamination; or
- That is an unexpected or unforeseeable event that may related to the transmission or potential transmission of a communicable disease or may lead to HCT/P contamination

HCT/P Deviation Reporting (21 CFR 1271.350(b))

All HCT/P deviations related to a distributed HCT/P

- Must be investigated by the manufacturer
- Must report any such HCT/P deviation
  - That occurred in that facility or in a facility that performed a a manufacturing step for the facility under contract, agreement, or other arrangement
  - Only those related to "Core CGTPs"

When, Who, How?

- You must report each such HCT/P deviation *that relates to a core CGTP*…within 45 days of the discovery of the event.
- Establishments that manufacture HCT/Ps
- If the HCT/P deviation occurred in your facility or in a facility that performed a mfr step for you under
- Report on Form FDA 3486, electronically or by mail http://www.fda.gov/cber/biodev/biodev.htm

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

BIOLOGICAL PRODUCT DEVIATION REPORT

FDA USE ONLY	
Date Received:	
Date Reviewed:	
BPD ID:	
BPD No.	

* indicates required information

A. FACILITY INFORMATION

1. Reporting Establishment Information

* Reporting Establishment Name

* Street Address Line 1

Street Address Line 2

* City	* State
Country	* Zip Code

* Point of Contact

* Telephone #
( )

E-mail

2. * Reporting Establishment Identification Number

FDA Registration #

CLIA #

3. If the BPD occurred somewhere other than the above facility, please complete this Section and Section A4, otherwise continue onto Section B1.

* Establishment Name

Street Address Line 1

Street Address Line 2

* City	* State
* Country	Zip Code

4. Establishment Identification Number:

FDA Registration #

CLIA #

B. BIOLOGICAL PRODUCT DEVIATION (BPD) INFORMATION

1. Establishment Tracking #

2. Date BPD Occurred

3. * Date BPD Discovered

4. * Date BPD Reported

5. * Description of BPD *(use Page 2 for additional space)* Go To Page 2

6. * Description of Contributing Factors or Root Cause *(use Page 3 for additional space)* Go To Page 3

7. * Follow-Up *(use Page 4 for additional space)* Go To Page 4

8. * Please Enter the 6 Character BPD Code

C. UNIT / PRODUCT INFORMATION

Please check the type of product:

Blood ☐ (Continued on Page 5)

Non-Blood ☐ (Continued on Page 6)